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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,256	03/26/2004	Robert Joseph Sarama	9587	1649

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EXAMINER
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FISHER, ABIGAIL L

ART UNIT	PAPER NUMBER
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1609

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08/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/811,256

Applicant(s)

SARAMA ET AL.

Examiner

Abigail Fisher

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date March 26 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-20 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of vitamins in the reply filed on July 18 2007 is acknowledged. The species election is withdrawn.

#### ***Specification***

The disclosure is objected to because of the following informalities: The use of the trademarks LAKSO WURSTER has been noted in this application (Specification, page 6, paragraph 6, and page 9, example 1). However it is unclear if the trademark is LAKSO™ or WURSTER™ or LAKSO WURSTER™. Other trademarks used are: SIGMA® (Specification, page 10, example 2); BASF® (Specification, page 10, example 1 and 2); ADM® (Specification, page 10, example 2); AAPER® (Specification, page 10, example 1 and 2); J.T. BAKER® (Specification, page 10, example 1 and 2). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 19, and 20 are ambiguous as written. It is unclear what exactly constitutes pH resistance. The specification refers to a parameter, which refers to the measurement of pH, therefore it is unclear if by pH resistance what is meant is a particular pH of solution or a different property. The specification does not define "pH resistance". Therefore, one of ordinary skill in the art at the time of the invention would be unable to understand the metes and bounds of this term.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11-12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarama et al. (PGPUB, US 2003/0045473 A1, published March 6 2003).

For claims 1-5: Sarama et al. discloses in Example 1 (page 7, right column, paragraph 0064) a composition consisting of a sterol (phytosterol), a solvent (hexane/ethanol). In the instant application the azeotropic mixture of hexane and

ethanol (claim 5) is disclosed. This claim depends upon claim 4, which subsequently depends on claim 3. Therefore by applicants own admission the azeotropic mixture of hexane and ethanol meets the requirements put forth in claims 3 and 4 of a Hildebrand Solubility Index and Snyder Polarity Index.

For claims 11-12, 14-15: Also included in Sarama et al. Example 1 is the addition of L-arginine, which is an amino acid. The coating agent listed above comprising a phytosterol and a solvent is included with an ingestible substrate, an amino acid. Additionally included in example 1 is the statement that in the preparation of the composition the inlet air temperature is adjusted between about 100 °C and about 140 °C, this would indicate that the coated substrate has a thermal resistance that meets the qualification required by claim 15 in the instant application.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-10, 13, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. (PGPUB, US 2003/0045473 A1, published March 6 2003) in view of the Sigma-Aldrich online catalog ([http://www.sigmaaldrich.com/Area\\_of\\_Interest/The\\_Americas/United\\_States.html](http://www.sigmaaldrich.com/Area_of_Interest/The_Americas/United_States.html)) and in view of Gordon et al. (The Chemist's Companion, 1973, p 27).

For claim 6: Sarama et al. discloses the use of an azeotropic solvent mixture of hexane and ethanol. An azeotropic solvent mixture comprising ethyl acetate and ethanol is not explicitly mentioned. Gordon et al. discloses various azeotropic mixtures containing ethanol. Depending on the desired polarity as well as the desired boiling point of the azeotropic mixture, one skilled in the art would be motivated to try the azeotropic mixture of ethyl acetate and ethanol. Both ethyl acetate and hexane are common solvents used by one skilled in the art and subsequently would be expected to have a reasonable expectation of success as well as obtaining predictable results.

For claims 7-10: Sarama et al. discloses a coating agent consisting of a phytosterol and a solvent, as mentioned above. In the specification (page 4, right

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column, [0040]) Sarama et al. discloses that phytosterols typically contain a mixture of sitosterol and other sterols such as campesterol, stigmasterol, and various avenasterols. Therefore by this definition it is understood that the phytosterols used in the examples (Example 1) would contain sitosterol and realistically contain stigmasterol. The Sigma Aldrich online catalog indicates that sitotsterol has a melting point of 136-140 °C, which anticipates the range of claim 7 of the instant application. This reference is only being used to indicate the physical properties of sitotsterol. Therefore for claim 7 of the instant application the sterols comprise a sterol with a melting point from about 40 °C to about 170 °C (sitotsterol) and stigmasterol. In Example 1 of Sarama et al. the percentage of phytosterol used is 17%, which anticipates the range in claim 9 of the instant application. This example also anticipates claim 10 of the instant application because 17% (of Sarama et al.) is about 15%. In Example 1 of Sarama et al. the solvent percentage is 90% of an azeotropic mixture, which additionally anticipates the range in both claims 9 and 10 of the instant application.

For claim 13: With the understanding of what constitutes phytosterols mentioned in Example 1 of Sarama et al., example 1 additionally indicates that L-arginine is added which would be an ingestible substrate.

For Claims 16-20: Sarama et al. discloses a coating agent that meets the requirements established by claims 1-15 of the instant application, therefore it would be expected that the requirements of pH resistance, oxidative resistance, and water solubility as established by claims 16-21 are inherent properties of the composition. Since, as stated in the rejection above, it is unclear what is exactly meant by pH

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resistance. If pH resistance actually refers to pH, then Sarama et al. discloses compositions (specification, page 13, right column, [0130]) that have a pH of about 2 to about 8 which reads on claims 16, 19 and 20 in the instant application.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail Fisher whose telephone number is 571-270-3502. The examiner can normally be reached on M-Th 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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